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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

NATNITHITHADHA, NAVIN

ART UNIT PAPER NUMBER

3736

DATE MAILED: 12/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/645,328

Applicant(s)

LLINAS, RODOLFO R.

Examiner

Navin Natnithithadha

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6-25 is/are rejected.
- 7) ☒ Claim(s) 5 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 07292004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claim 5 is objected to because of the following informalities:

It is not clear as to whether the step of monitoring a further signal on the further electrode is done after the step of applying a stimulus to the neural tissue. The Examiner suggests amending the claim to - - monitoring a further signal on the further electrode after applying a stimulus to the neural tissue - -. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 3, 4, 20, and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not give sufficient disclosure for the method of claims 3 and 4 including the electrode is inserted into the blood vessel at a point upstream of a

junction with another blood vessel, and a sensing end of the electrode is deployed to a point downstream of the junction.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-4, 10, 11, 14, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Kovacs et al, US 5,883,603 A.

In regards to claims 1, 2, 10 and 14, Kovacs teaches a method and device for sensing the activity of neural tissue (see fig. 10 and col. 15, lines 50-57), comprising: placing electrode 120 and 122 proximate to the neural tissue using an intra-arterial catheter 148 (see fig. 12 and col. 18, lines 15-20); and monitoring a signal on the electrodes 120 and 122, wherein a signal on the electrode is indicative of the activity of the neural tissue (see col. 15, lines 51-57).

As to claim 2, Kovacs teaches a sensing end of electrodes 130 and 132 (see fig. 10).

As to claims 3 and 4, Kovacs teaches an intra-arterial catheter 148 in which inherently is capable of inserting electrodes into an artery at the position claimed.

As to claims 11 and 15, Kovacs teaches a control circuit 36 (see col. 16, line 4).

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4. Claims 18-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Schulman et al, US 5,651,767 A.

In regards to claim 18, Schulman teaches a method of stimulating neural tissue (see col. 1, lines 11-16), comprising: placing an electrode 40' in a blood vessel; providing a signal on the electrode for stimulation (see col. 10, line 16 and claim 15).

As to claim 19, Schulman teach the electrode 40' being placed in the blood vessel (see fig. 2).

As to claims 20 and 21, Schulman teaches placing an electrode 40' in a blood vessel, which inherently is capable of placing electrodes into a blood vessel at the position claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kovacs et al, US 5,883,603 A, as applied to claim 1 above, and further in view of Lieber et al, US 2002/0117659 A1.

In regards to claims 6 and 7, Kovacs does not teach nano-electrode or an array of nano-electrodes. However, Lieber teaches nano-sensors comprising nano-electrodes 36 (see fig. 1a and paragraph 133). It would have been obvious for one of

ordinary skill in the art at the time the invention was made to modify Kovacs's electrodes in order to have electrodes that are of sufficient size to be placed near neural tissue.

As to claim 8, Kovacs teaches electrodes 120 and 122 having different lengths (see fig. 10).

6. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kovacs et al, US 5,883,603 A, in view of Lieber et al, US 2002/0117659 A1, as applied to claim 6 above, and further in view of Imram, US 5,391,147 A.

As to claim 9, Kovacs and Lieber do not teach a cup-like end to an electrode. However, a cup-like end to an electrode is a well-known structure to electrodes. For example, Imram teaches a catheter comprising an electrode 221 having a cup shaped end (see fig. 19 and col. 8, lines 47-52). It would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Kovacs's electrode to have a cup shaped end in order to accurately sense the activity of neural tissue.

7. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kovacs et al, US 5,883,603 A, as applied to claim 12 above, and further in view of Hoek, US 6,615,067 B2.

As to claims 12 and 13, Kovacs teach low-noise differential amplifiers (see col. 16, line 2). Kovacs does not teach a digital converter which includes a Schmitt trigger. However, use of a Schmitt trigger for converting analog signals to digital signals is well known in the art. For example, Hoek teaches a Schmitt trigger 307 connected to a filter

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306 (see col. 6, lines 24-29). It would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Kovacs circuitry to include a Schmitt trigger in order to have accurate digital processing of an electrode signal.

8. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kovacs et al, US 5,883,603 A, as applied to claim 15 above, and further in view of John, US 4,913,160 A.

As to claim 16, Kovacs teach low-noise differential amplifiers (see col. 16, line 2). Kovacs does not teach a plurality of digital converters and a multiplexer. However, digital processing of a plurality analog signals using digital converters and a multiplexer is well known in the art. For example, John teaches a plurality of electrode signals 11 amplified by amplifiers 14 that are inputted to an A/D converter/multiplexer 33, wherein the signals are process digitally by a microprocessor 35 (see fig. 1 and col. 4, lines 24-31). It would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Kovacs circuitry to include an A/D converter/multiplexer in order to have accurate digital processing of an electrode signal.

9. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kovacs et al, US 5,883,603 A, and further in view of John, US 4,913,160 A, as applied to claim 16 above, and further in view of Lieber et al, US 2002/0117659 A1.

As to claim 17, Kovacs does not teach nano-electrode(s) having a nano wire and a micro-wire. However, Lieber teaches electrodes 36 connected to nanowire 38 and

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electrical connections 22 (see fig. 1a and see paragraph 135). It would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Kovacs's electrodes in order to have electrodes that are of sufficient size to be placed near neural tissue.

10. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman et al, US 5,651,767 A, as applied to claim 18 above, and further in view of Lieber et al, US 2002/0117659 A1.

As to claim 22, Schulman does not teach a nano-electrode. However, Lieber teaches nano-sensors comprising nano-electrodes 36 (see fig. 1a and paragraph 133). It would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Schulman's electrodes in order to have electrodes that are of sufficient size to be placed near neural tissue.

11. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman et al, US 5,651,767 A, as applied to claim 18 above, in view of Lieber et al, US 2002/0117659 A1, and further in view of Daniel et al, US 6,622,731 B2.

As to claims 23 and 24, Schulman does not teach an array of nano-electrodes having different lengths. Lieber teaches nano-electrodes as discussed above for claim 22. Daniel teaches a catheter 198 comprising nerve stimulation electrodes 176 and 180 having different advancement lengths from catheter 198 (see col. 15, lines 21-26, and col. 29, lines 56-58). It would have been obvious for one of ordinary skill in the art at the

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time the invention was made to modify Schulman's device in order to effectively stimulate a tissue site or organ.

12. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman et al, US 5,651,767 A, in view of Lieber et al, US 2002/0117659 A1, as applied to claim 22 above, and further in view of Imram, US 5,391,147 A.

As to claim 25, Schulman and Lieber do not teach a cup-like end to an electrode. However, a cup-like end to an electrode is a well-known structure to electrodes. For example, Imram teaches a catheter comprising an electrode 221 having a cup shaped end (see fig. 19 and col. 8, lines 47-52). It would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Schulman's electrode to have a cup shaped end in order to properly stimulate neural tissue.

Allowable Subject Matter

13. Claim 5 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

14. The following is a statement of reasons for the indication of allowable subject matter:

As to claim 5, the prior art of record does not teach the method of claim 1, including applying a stimulus to the neural tissue and comparing a second signal after stimulation of the neural tissue with the first signal before stimulation.

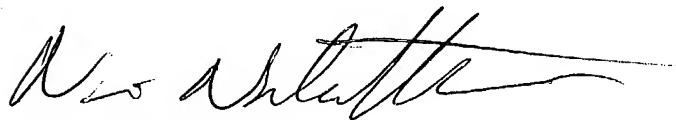
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Conclusion


15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Navin Natnithithadha whose telephone number is (571) 272-4732. The examiner can normally be reached on Monday-Friday, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Navin Natnithithadha
Patent Examiner
GAU 3736
November 23, 2004


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